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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/252,384	06/01/1994	C. STEVEN MCDANIEL	5842-00503	3543

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/252,384	MCDANIEL ET AL.	
	Examiner	Art Unit	
	YONG D. PAK	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73 and 75-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73 and 75-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of 07/928,540, now abandoned, which is a divisional of 07/344,258, now abandoned.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2008 has been entered.

The amendment filed on August 22, 2008, amending claim 73, has been entered.

Claims 73 and 75-82 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on August 22, 2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The Sequence Listing filed March 5, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The Sequence Listing contains a polynucleotide having the nucleotide sequence of SEQ ID NO:1 and its encoded polypeptide having the amino acid sequence of SEQ ID NO:2. The nucleic acid sequence of SEQ ID NO:1 and the amino acid sequence of SEQ ID NO:2 were not described in the application as originally filed nor in any of its parent applications. The specification as filed contains disclosure of a polynucleotide ("opd gene" of Figure 1) encoding an organophosphorus acid anhydrase which is different from the polynucleotide encoding the organophosphorus acid anhydrase of SEQ ID NO:2 submitted in the Sequence Listings filed on May 21, 2003, October 13, 2004, March 10, 2005 and November 7, 2005. Further, none of the polynucleotide sequence and the polypeptide sequences of SEQ ID NO:1 and 2 disclosed in the four Sequence Listings are identical to each other.

Applicant is required to cancel the new matter in the reply to this Office Action.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that the originally filed sequence listing was a "subsequence... and was filed with minor errors due to the difficulty in obtaining accurate gene sequences in 1988-1989... applicants assert one skilled in the art would apprised based on the specification that the applicants had possession of SEQ ID NOs:1 and 2 listed in

the sequence listing filed on November 7, 2005. Examiner respectfully disagrees. The "subsequence" of the opd gene filed in error (SEQ ID NO:3) and the "correct" opd gene (SEQ ID NO:1) share only 83% identity. The encoded opd protein filed in error (SEQ ID NO:4) and the "correct" opd protein (SEQ ID NO:4) also share only 84% identity and the latter opd protein is longer by four amino acids. One skilled in the art would not have recognized the existence of the error since the specification as originally filed explicitly discloses a nucleotide sequence of an *opd* gene and one skilled in the art would also not recognize the appropriate correction. Further, if in fact the "subsequence" opd gene of SEQ ID NO:3 is the incorrect nucleotide sequence, it is not clear why applicants are claiming *opd* gene of SEQ ID NO:3 and not the "correct" *opd* gene of SEQ ID NO:2.

Hence the objection is maintained.

Claim Rejections - 35 USC § 112- 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Withdrawn Rejection

In view of the amendment of claim 73, the rejection of claims 73 and 75-82 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been **withdrawn**.

In view of the amendment of claim 73, the rejection of claims 73 and 75-82 under 35 U.S.C. 112, first paragraph,, as failing to comply with the enablement requirement, has been **withdrawn**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 73, 75 and 77-81 were rejected under 35 U.S.C. 102(e) as being anticipated by Seder et al. (US Patent No. 5,484,728).

In view of the fact that (A) Seder et al. do not teach a polynucleotide comprising the nucleotide sequence of SEQ ID NO:3 and encoding a polypeptide having organophosphorous acid anhydrase activity, and (B) the claims, as amended, are drawn to a polynucleotide comprising the nucleotide sequence of SEQ ID NO:3 and encoding a polypeptide having organophosphorous acid anhydrase activity, the rejection has been **withdrawn**.

Claims 73, 75, 77-78, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulbry et al.

Claims 73, 75, 77-78, and 80 are drawn to a polynucleotide comprising the nucleotide sequence of SEQ ID NO:3 and a coding sequence encoding an organophosphorous acid anhydrase, plasmid, expression vector comprising said polynucleotide, and a bacterial cell transformed with said expression vector.

Mulbry et al. (Applied and Environmental Microbiology, May 1986, p. 926-930 - PTO-1449) discloses an *opd* gene cloned from *Pseudomonas diminuta* (pCMS1) encoding an organophosphorous acid anhydrase, plasmid and expression vector comprising said polynucleotide, and a bacterial cell transformed with said expression vector (2nd column on page 927 "Cloning of the *opd* gene sequence from *P. diminuta*"). The opd gene of SEQ ID NO:3 of the instant invention is also cloned from P. diminuta (pCMS1) (specification on page 21, lines 1-21). Therefore, Examiner takes the position that the *opd* gene of Mulbry et al. inherently possesses the same material structure and functional characteristics as the *opd* gene of the claimed invention since (1) both genes

are isolated from the same source, *P. diminuta* pCMS1, (2) both genes encode polypeptides having organophosphorous acid anhydrase activity, and (3) the Office does not have facilities for examining and comparing applicant's enzyme with the enzyme of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the *opd* gene of the prior art does not possess the same material structure and functional characteristics of the claimed *opd* gene). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Figzgerald* et al., 205 USPQ 594. Therefore, the reference of Mulbry et al. anticipates claims 73, 75, 77-78, and 80.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that since claim 73 has been amended to recite "the nucleotide sequence of SEQ ID NO:3" and Mulbery does not teach or suggest the nucleotide sequence of SEQ ID NO:3, the reference of Mulbery does not anticipate claims 73, 75, 77-78, and 80. Examiner respectfully disagrees. Even though Mulbery et al. does not explicitly disclose the nucleotide sequence of SEQ ID NO:3, Mulbery et al. does disclose an *opd* gene cloned from *Pseudomonas diminuta* (pCMS1) encoding an organophosphorous acid anhydrase (2nd column on page 927 "Cloning of the *opd* gene sequence from *P. diminuta*"). Both the opd gene of Mulbery et al. and the opd gene of SEQ ID NO:3 of the instant invention were cloned from *P. diminuta* (pCMS1), using a 1.3-kb *PstI* insert (specification on pages 21-22 and pages 927-928 of Mulbery et al). Therefore, Examiner takes the position that the *opd* gene of Mulbry et al. inherently

possesses the same material structure and functional characteristics as the *opd* gene of the claimed invention since (1) both genes are isolated from the same source, *P. diminuta* pCMS1, (2) both genes encode polypeptides having organophosphorous acid anhydrase activity, and (3) the Office does not have facilities for examining and comparing applicant's enzyme with the enzyme of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the *opd* gene of the prior art does not possess the same material structure and functional characteristics of the claimed *opd* gene). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Figzgerald* et al., 205 USPQ 594.

Hence the rejection is maintained.

Claims 73, 75, 77-78, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Serdar et al.

Claims 73, 75, 77-78, and 80 are drawn to a polynucleotide comprising the nucleotide sequence of SEQ ID NO:3 and a coding sequence encoding an organophosphorous acid anhydrase, plasmid, expression vector comprising said polynucleotide, and a bacterial cell transformed with said expression vector.

Serdar et al. (BIO/TECHNOLOGY VOL. 3, June 1985 - PTO-1449) discloses an *opd* gene cloned from *Pseudomonas diminuta* (pCMS1) encoding an organophosphorous acid anhydrase, plasmid and expression vector comprising said polynucleotide, and a bacterial cell transformed with said expression vector (pages 567-

570). The opd gene of SEQ ID NO:3 of the instant invention is also cloned from P. diminuta (pCMS1) (specification on page 21, lines 1-21). Therefore, Examiner takes the position that the *opd* gene of Serdar et al. inherently possesses the same material structure and functional characteristics as the *opd* gene of the claimed invention since (1) both genes are isolated from the same source, *P. diminuta* pCMS1, (2) both genes encode polypeptides having organophosphorous acid anhydrase activity, and (3) the Office does not have facilities for examining and comparing applicant's enzyme with the enzyme of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the *opd* gene of the prior art does not possess the same material structure and functional characteristics of the claimed *opd* gene). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Figzgerald* et al., 205 USPQ 594. Therefore, the reference of Serdar et al. anticipates claims 73, 75, 77-78, and 80.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that since claim 73 has been amended to recite "the nucleotide sequence of SEQ ID NO:3" and Mulbery does not teach or suggest the nucleotide sequence of SEQ ID NO:3, the reference of Mulbery does not anticipate claims 73, 75, 77-78, and 80. Examiner respectfully disagrees. Even though Mulbery et al. does not explicitly disclose the nucleotide sequence of SEQ ID NO:3, Mulbery et al. does disclose an *opd* gene cloned from *Pseudomonas diminuta* (pCMS1) encoding an organophosphorous acid anhydrase (2nd column on page 927 "Cloning of the *opd* gene

sequence from *P. diminuta*"). Both the opd gene of Mulbery et al. and the opd gene of SEQ ID NO:3 of the instant invention were cloned from *P. diminuta* (pCMS1) (specification on pages 21-22 and pages 568-569 of Serdar et al). Therefore, Examiner takes the position that the *opd* gene of Serdar et al. inherently possesses the same material structure and functional characteristics as the *opd* gene of the claimed invention since (1) both genes are isolated from the same source, *P. diminuta* pCMS1, (2) both genes encode polypeptides having organophosphorous acid anhydrase activity, and (3) the Office does not have facilities for examining and comparing applicant's enzyme with the enzyme of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the *opd* gene of the prior art does not possess the same material structure and functional characteristics of the claimed *opd* gene). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Figzgerald* et al., 205 USPQ 594.

Hence the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 76, 79 and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulbry et al. **or** Serdar et al. (BIO/TECHNOLOGY) in view of Wong et al.

Claims 76, 79 and 81-82 are drawn to a viral vector and a mammalian/eukarytoic cell comprising the nucleotide sequence of SEQ ID NO:3.

Mulbry et al. **or** Serdar et al. (BIO/TECHNOLOGY) discloses a nucleotide sequence of SEQ ID NO:3, as discussed above.

The above references do not teach a viral vector or a mammalian/eukaryotic cell comprising said nucleotide sequence.

However, viral vectors and mammalian/eukaryotic host cells for the expression of heterologous proteins is well known. Wong et al. (U.S. Patent No. 4,849,355 – form

PTO-892) discloses viral vectors and mammalian host cells comprising a heterologous polynucleotide (Columns 3-4 and claims 1-10).

Therefore, combining the teachings of Mulbry et al. **or** Serdar et al. (BIO/TECHNOLOGY) and Wong et al., it would have been obvious to one having ordinary skill in the art make a viral vector or mammalian host cell comprising the polynucleotide of Mulbry et al. **or** Serdar et al. (BIO/TECHNOLOGY). One of ordinary skill in the art would have been motivated to make such a construct to test expression of the claimed polypeptide as a heterologous protein in a mammal. One of ordinary skill in the art would have had a reasonable expectation of success since Wong et al. teaches how to make such a construct and successfully express heterologous proteins in mammals.

Therefore, the above references render claims 76, 79 and 81-82 *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that the claims are not obvious because Serdar et al. nor Mulbery et al. teach a polynucleotide comprising the nucleotide sequence of SEQ ID NO:3. Examiner respectfully disagrees, see discussion above.

Hence the rejection is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652